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SUPREME COURT, U.S.
FILED
JAN 3 - 2005
OFFICE OF THE CLERK

No. 04-579

IN THE

Supreme Court of the United States

WAYNE CHARLES OKEN,

Petitioner,

v.

THE MONSANTO COMPANY, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF IN OPPOSITION

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STATEMENT PURSUANT TO RULE 29.6

DowElanco was an Indiana general partnership formed October 31, 1989 between Rofan Services Inc. and Epco, Inc. Rofan Services Inc. is a wholly-owned subsidiary of The Dow Chemical Company ("Dow"). Epco, Inc. was a wholly-owned subsidiary of Eli Lilly and Company, but Epco, Inc. no longer exists. On July 1, 1997, DowElanco became DowElanco LLC, a Delaware limited liability company wholly owned by Dow. On January 1, 1998, DowElanco LLC's name was changed to Dow AgroSciences LLC, which remains a wholly owned subsidiary of Dow.

Scotts Company does not have a parent corporation and no publicly held company owns more than 10% of its stock.

The Monsanto Company involved in the subject litigation is a wholly-owned subsidiary of Pfizer Inc.

Home Depot U.S.A., Inc. does not have a parent corporation and no publicly held company owns more than 10% of its stock.

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STATEMENT OF THE CASE

Introduction

"While this Court decides questions of public importance, it decides them in the context of meaningful litigation." *The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959). This is not such a case.

Petitioner Wayne Charles Oken ("Oken") is incorrect to argue that because this Court granted *certiorari* review in *Bates v. Dow AgroSciences LLC*, 124 S. Ct. 2903 (2004) (No. 03-388) (oral argument scheduled Jan. 10, 2005), the similarities between the issues upon which he seeks review, and the issues likely to be decided in *Bates*, weigh towards *certiorari* review of his case as well. Oken is correct that both cases involve consideration of the express preemptive effect of 7 U.S.C. § 136v(b), the express preemption clause in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. Both cases also present questions of implied preemption through conflict with FIFRA's statutory structure, FIFRA's implementing regulatory regime established and enforced by the United States Environmental Protection Agency ("EPA") and, particularly, through conflict with 40 C.F.R. § 152.130(a) ("A registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency.").

Oken's case and *Bates* are also substantially similar in that both appear before this Court on fully-developed summary judgment records. *Bates*, therefore, presents at least some claims (although each of them are label-based) that do not involve abstract or hypothetical questions such as those

presented in other recent preemption cases this Court has considered. *E.g.*, *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (decided on the Illinois state analogue to FED. R. CIV. P. 12(b)(6)); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("[T]he preemption issue was decided on the basis of the pleadings"). Oken's case, however, is much different.

When Respondent Dow AgroSciences LLC ("DAS") moved for summary judgment on the grounds that federal law preempted Oken's personal injury claims, Oken responded with a mountain of lay evidence and unauthenticated documents and one putative expert affidavit, all in an attempt to demonstrate (1) that Oken had indeed suffered a pesticide-related personal injury; and (2) that the two pesticide products accused (DAS's manufacturing grade product sold in bulk and an end-use over-the-counter product that may have incorporated that product) were defective.

When DAS objected to and moved to strike Oken's evidence, Oken agreed that DAS's objections were well-taken, and he voluntarily withdrew all of his documentary evidence and all but an immaterial snippet of his lay affidavit evidence. Oken also voluntarily conceded that his sole expert's affidavit was inadmissible. Oken's withdrawal of his lay evidence and his documentary submissions, and his concession that his expert's affidavit was inadmissible, left him with but one piece of evidence — his own solemn admission against interest that his treating physician diagnosed him as having "no evidence of toxicity."

In short, Oken's voluntary litigation decisions, and his other evidentiary defaults, including his total failure "to provide expert testimony that the product was defective and evidence that the product caused the injury of which [he]

complains," *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) (citations omitted), left him with no viable state-law claims for federal law to preempt. While the district court based its decision primarily on FIFRA preemption, but did address some of the state-law reasons why Oken's claims necessarily failed, and while the court of appeals affirmed solely on the basis of federal preemption, the fact remains that Oken's own evidentiary failures and his fatal admission against interest conclusively disproved the entirety of his case.

Even if Oken's challenge to FIFRA preemption were to succeed, therefore, it would change nothing as to the correct termination of his individual case. Oken provides no reason why this Court should "disturb the settled rule that, in reviewing the decision of a lower court, it must be affirmed if the result is correct although the lower court relied upon a wrong ground or gave a wrong reason." *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) (citation and internal quotation marks omitted).

Accordingly, Oken's petition should be denied for the straightforward reason that he presents only abstract and hypothetical questions regarding express and implied preemption under FIFRA and its implementing regulatory regime, none of which need be reached. "It is not the habit of this Court to decide questions of a constitutional nature unless absolutely necessary to a decision of the case." *Burton v. United States*, 196 U.S. 283, 295 (1905).

But there is one more important reason why this case is very different from *Bates* and why Oken's petition should be denied. This reason is provided by an unexpected source — the preeminent national plaintiffs' bar association.

In an *amicus* brief filed on September 13, 2004, in support of the Petitioners in *Bates*, the Association of Trial Lawyers of America ("ATLA") identified itself as "a voluntary national bar association whose approximately 50,000 trial lawyer members primarily represent individual plaintiffs in civil actions brought under state tort law." *Amicus Curiae* Brief of the Association of Trial Lawyers of America in Support of Petitioners (filed U.S. No. 03-388) at 1 ("Identity and Interest of *Amicus Curiae*"). In its *amicus* brief, ATLA stated that express preemption of personal injury claims like Oken's was entirely correct, arguing only that a narrow exception to FIFRA preemption should be created for label-based crop damage claims:

> [A]ctions by Congress and the EPA removed property damage claims from the scope of FIFRA preemption. They draw a clear distinction between state claims for personal injury or environmental damage and those for property damage. The former are label-based because the label process requires review and approval of data relating to hazards to humans and the environment.

Id. at 3.

> The effect of these congressional and EPA actions was to carve a small niche out of FIFRA's preemptive scope. . . .
>
> Congress and the EPA have effectively drawn a clear distinction, for preemption purposes, between state claims made for personal injury or environmental damage and those made for property damage. The former are prima facie

> label-based because the label process requires review and approval of data relating to the health of humans and the environment.

Id. at 9-10.

Thus, while Oken's individual counsel argue against FIFRA preemption in the context of personal injury claims, 50,000 of their plaintiffs'-dedicated ATLA colleagues disagree, accepting FIFRA preemption in that context to be a correct application of 7 U.S.C. § 136v(b). Indeed, ATLA and its 50,000 members of the plaintiffs' bar have separately urged this Court to so hold. Respondents here disagree with ATLA's opinion that the preemptive effect of FIFRA § 136v(b)'s plain text tolerates exceptions to it based on any artificial distinction between state law requirements for labeling imposed by label-based property damage claims as contrasted with label-based personal injury claims. Respondents do agree with ATLA's 50,000 plaintiffs' lawyers, however, that if Oken had preserved any state law claims at all, they would be label-based and FIFRA would expressly and impliedly preempt them.

There is, therefore, a significant consensus on the applicability of FIFRA preemption in personal injury cases. This conclusion is punctuated by the fact that Oken points to only one state court decision, and to no federal decision, that has held otherwise since this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). *See* Pet. at 10 (citing *Sleath v. West Mont Home Health Servs., Inc.*, 16 P.3d 1042 (Mont. 2000), *cert. denied sub nom. Dow AgroSciences LLC v. Sleath*, 534 U.S. 814 (2001)).

It is anomalous, however, for Oken to cling to a Montana state decision as proof of a split in authority meriting *certiorari* review when his home state's courts embrace FIFRA preemption in harmony with the court of appeals here. *See, e.g., Palmas Y Bambu, S.A. v. E. I. DuPont de Nemours & Co., Inc.*, 881 So. 2d 565, 577-79 (Fla. Dist. Ct. App. 2004); *ISK Biotech Corp. v. Douberly*, 640 So. 2d 85, 88 (Fla. Dist. Ct. App. 1994) ("FIFRA preempts all state common law actions that are associated in any way with a claim of inadequate labeling."), *review denied*, 651 So. 2d 1194 (Fla. 1995). Thus, there is no arguable split in authority between Oken's home state courts and the regional federal circuit such as that presented in *Bates*. And, unlike the Petitioners in *Bates*, Oken here makes no argument at all that his case would have been decided differently by Florida's state courts than it was by the courts below. For all these reasons, Oken presents no compelling circumstances requiring *certiorari* review.

STATEMENT OF THE CASE

1. This action arises out of Oken's complaint seeking damages for alleged personal injuries. Oken, who had a history of significant health problems and was pacemaker-dependent, alleged that he purchased two bags of an over-the-counter pesticide, Ortho Dursban Lawn & Garden Insect Control ("Ortho Dursban"), from Respondent Home Depot U.S.A., Inc. ("Home Depot") on October 26, 1996, and he used them on April 13, 1997, to control an infestation of ants in his lawn. Despite the fact that the record directly contradicts his statement, Petitioner argues:

> Shortly thereafter, petitioner began to experience the signs and symptoms of acute cholinergic poisoning. He required immediate hospitalization,

> where he had to be intubated to assist his breathing, and has suffered severe neurological problems since.

Pet. at 2.

Oken's own treating physician, however, rejected Oken's self-diagnosis, concluding, "Insecticide exposure *with no evidence of toxicity.* Adequate cholinesterase levels."

Oken offered his treating physician's conclusion in his evidentiary submission in opposition to DAS's motion for summary judgment and that admission against interest conclusively disproves the entirety of his case. Similarly, there is not a scrap of evidence in the record to support Oken's argument that "he had to be intubated to assist his breathing, and has suffered severe neurological problems since" or that if those problems did exist, they can be causally related to his use of Ortho Dursban as alleged.

2. Dursban® is the registered trademark for a group of insecticides developed, manufactured and marketed by The Dow Chemical Company ("Dow") prior to October 31, 1989, and by DowElanco and then DAS since that date. The active insecticidal ingredient in all Dursban products is chlorpyrifos. DAS sells a variety of technical grade chlorpyrifos products to formulators under various names. Dursban HF Insecticidal Concentrate ("Dursban HF") is one such chlorpyrifos-containing technical grade formulation.

At all material times, Dursban HF was registered with the EPA pursuant to FIFRA. Dow received a stamped and accepted product label from the EPA upon registration of the product. The EPA-accepted Dursban HF label in place

during the pertinent period states that it is "For Manufacturing Use Only" and that:

> Because of their properties and intended uses, insecticidal formulations containing DURSBAN HF insecticide will require precautionary labeling differing from that given. Formulators should develop their own use and precautionary labeling, based on the properties and intended uses of their own finished formulations, and are responsible for obtaining EPA registration of these products. [1]

The Dursban HF label also provides:

WARNING

* * *

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

MAY BE FATAL IF SWALLOWED • EXCESSIVE ABSORPTION THROUGH SKIN MAY BE FATAL • CAUSES EYE IRRITATION • MAY CAUSE SKIN IRRITATION

* * *

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1. This label language is particularly important because it operates to discharge all of DAS's Florida state law duties to Oken as a matter of black-letter Florida law. *Shell Oil Co. v. Harrison*, 425 So. 2d 67 (Fla. Dist. Ct. App. 1982), *review denied*, 436 So. 2d 98 (Fla. 1983). *See* Section VII.

STATEMENT OF PRACTICAL TREATMENT:

* * *

NOTE TO PHYSICIAN: Chlorpyrifos is a cholinesterase inhibitor. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate significance of exposure (baseline data are useful).

DAS observes strict quality assurance manufacturing protocols to assure that each production batch of technical grade chlorpyrifos and Dursban HF is in compliance with DAS's production specifications, the EPA-approved confidential statements of formula, and EPA's regulations governing product quality and consistency.[2] At all times relevant hereto, DAS has always sold Dursban HF with EPA-accepted labels affixed to the product's containers at the time of the sale, and has sold it only in bulk to formulators such as The Solaris Group ("Solaris"), formerly a division of the Agricultural Group of Respondent the Monsanto Company ("Monsanto"). Oken does not dispute these facts.

3. Solaris originally registered Ortho Dursban as "Ortho-Klor 1% Dursban Lawn & Soil Granules" under EPA registration number 239-2570. Solaris notified EPA per PR Notice 95-2 of the assumed business name for this product, "Ortho Dursban Lawn & Garden Insect Control," on January 10, 1996. Monsanto at all times sold Ortho Dursban with the EPA-approved label affixed to the product at the time of sale. (The Ortho Dursban label is reproduced in an appendix

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2. Indeed, Oken has voluntarily abandoned any claim that any of the accused products here had a manufacturing defect.

to the court of appeals' opinion. *See* Pet. App. at 5a-8a.) Dursban HF and Ortho Dursban were also registered by the Florida Department of Agriculture and Consumer Services pursuant to the Florida Pesticide Law. Oken does not dispute these facts.

Neither DAS nor its predecessors designed, made or sold "Ortho-Klor 1% Dursban Lawn & Soil Granules" or Ortho Dursban. Dursban HF, however, may have been used as an active ingredient in Ortho Dursban. Oken argues that "Dow and Monsanto were both integral participants in the design and marketing of Ortho Dursban Lawn & Garden Insect Control." Pet. at 3. There is not a scrap of evidence in the record (or outside of it), however, to support this factually-incorrect argument.[3]

4. Sometime between November 11, 1998 and January 21, 1999, Respondent the Scotts Company ("Scotts") acquired from Monsanto the assets of the Ortho product line,

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3. It is immaterial that DAS may have authorized Monsanto to use the Dursban trademark in connection with its end-use product. *See Harrison*, 425 So. 2d 67 (reversing verdict against bulk supplier of pesticide active ingredient to end-use product formulator despite bulk supplier's authorization to end-use formulator to use bulk supplier's trademark on label of end-use product). *See also, e.g.*, *Mobil Oil Corp. v. Bransford*, 648 So. 2d 119, 120 (Fla. 1995) ("In today's world, it is well understood that the mere use of franchise logos and related advertisements does not necessarily indicate that the franchisor has actual or apparent control over any substantial aspect of the franchisee's business. . . ."); *American Int'l Group, Inc. v. Cornerstone Businesses, Inc.*, 872 So. 2d 333, 336 (Fla. Dist. Ct. App. 2004) ("Florida law is clear that the use of a logo or trademark symbol alone cannot create an apparent agency.") (citations omitted).

which included Ortho Dursban. Because Scotts did not acquire the Ortho product line from Monsanto until January, 1999, it could not have designed, manufactured or sold the specific Ortho Dursban Oken allegedly purchased in October of 1996. Oken does not dispute these facts and he has never articulated any reason why Scotts could be liable to him; yet, he stubbornly refuses to voluntarily dismiss Scotts from these proceedings. Respondent Home Depot was a mere retailer of the Ortho Dursban and had no responsibility for the manufacture, packaging or labeling of that product.

REASONS FOR DENYING THE PETITION

The petition should be denied for the straightforward reason that all of Oken's claims failed under state law. The fact that the lower courts did not reach these state law reasons provides no basis for this Court to reach Oken's hypothetical and abstract arguments against federal preemption.

OKEN WITHDREW HIS LAY EVIDENCE, CONCEDED THAT HIS EXPERT'S AFFIDAVIT WAS INADMISSIBLE, AND ADMITTED HE HAD "NO EVIDENCE OF TOXICITY." FOR THESE REASONS, AMONG OTHERS, HIS CLAIMS, FAILED UNDER STATE LAW FOR LACK OF EVIDENCE.

I. Oken Withdrew His Lay Evidence And His Documentary Submissions.

Oken opposed DAS' motion for summary judgment by offering his own and his domestic partner Richard Hosford's affidavits, his answers to Epco, Inc.'s interrogatories, and a jumble of unauthenticated medical records. DAS properly objected because the affidavits and interrogatory answers

were rife with multiple layers of hearsay (FED. R. EVID. 801(c); 802; 805), were pregnant with inadmissible lay opinions (FED. R. EVID. 701(c); FED. R. CIV. P. 56(e)), and there was no foundation for the records or the hearsay and opinions within them (FED. R. EVID. 802; 803(6); 805; 702), among other objections.

Oken conceded that DAS made "reasonably sound objections" and affirmatively *withdrew* his offered evidence.[4] Oken's voluntary withdrawal of this proffered material left him without evidence to suggest that he suffered any harm. The same is true as to Oken's sole "expert" affidavit.

II. Oken Conceded That His Expert's Affidavit Was Inadmissible.

Oken understood that Florida law required him to oppose DAS's motion for summary judgment with expert evidence demonstrating (1) product defect and (2) medical causation. *See* Section III. To meet these required elements, Oken offered one putative "expert" affidavit in response to DAS' motion for summary judgment. When DAS objected and moved to strike it, Oken conceded its inadmissibility: "Dow correctly notes that Dr. Abou-Donia's Affidavit lacks

4. The sole exception Oken sought to preserve was his affidavit testimony "that the [Home Depot] 'sales person . . . said I did not need to wear gloves or a mask, just that I should read the label."' This alleged statement by an unidentified Home Depot employee was hearsay and unavailable as evidence against DAS, Monsanto or Scotts. *See* FED. R. EVID. 801(d)(2)(C)&(D). As to Home Depot, this testimony is irrelevant because Oken admitted that his sole expert's affidavit was inadmissible and, therefore, he had no evidence to demonstrate that the Ortho Dursban product label was itself defective or inadequate. *See* Sections II and III.

information that would be necessary to evaluate his testimony under the standards of Rule 702 and Daubert.[5] " *See Bragdon v. Abbott*, 524 U.S. 624, 653 (1998) ("Scientific evidence and expert testimony must have a traceable, analytical basis in objective fact before it may be considered on summary judgment.") (citation omitted).

Because Oken agreed that Dr. Abou-Donia's Affidavit was inadmissible, he was left with no expert evidence of any kind, a fatal defect under settled Florida state law.

III. Oken Has No Evidence Of A Product Defect Or Medical Causation.

Oken presented no competent expert testimony to support the existence of any defect claim of any kind, preempted or not. "[A] defect must be proven by expert testimony." *Alexander v. Danek Med., Inc.*, 37 F. Supp. 2d 1346, 1349 (M.D. Fla. 1999); *Savage v. Danek Med., Inc.*, 31 F. Supp. 2d 980, 983 (M.D. Fla.) (same), *aff'd*, 202 F.3d 288 (11th Cir. 1999) (mem.); *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1360 (M.D. Fla. 1999) ("Plaintiff [is] required to provide expert testimony that the product was defective and evidence that the product caused the injury of which [he] complains."); *Drury v. Cardiac Pacemakers, Inc.*, No. 8:02-CV-933-T-17MAP, 2003 WL 23319650, at *4 (M.D. Fla. June 3, 2003) ("Design defects must be proven by expert testimony.").

Oken's inadmissibility concession aside, it is uncontested that Dr. Abou-Donia is not a medical doctor, he never examined Oken, and he never pretended to offer an opinion

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5. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

that Oken's use of Ortho Dursban in fact caused Oken's injuries. All that aside, Dr. Abou-Donia's Affidavit was not competent to demonstrate a product defect or medical causation, general or specific:

> Dr. Abou-Donia is a research scientist who is engaged in research on adult chickens in order to study the delayed onset (OPIDN) [organophosphate induced delayed neuropathy] of the neurotoxic effects of TOCP [tri-ortho-cresyl phosphate] exposure. He does no work on humans, and performs strictly laboratory research.
>
> * * *
>
> Dr. Abou-Donia's conclusions are extrapolated from his work on chickens [and] ... cannot meet the threshold test of reliability under *Daubert* and therefore, may not be considered probative of causation.

Goewey v. United States, 886 F. Supp. 1268, 1280-81 (D.S.C. 1995), *aff'd*, 106 F.3d 390 (4th Cir. 1997) (mem.), *cert. denied sub nom. Goewey v. Fluor Daniel, Inc.*, 522 U.S. 1045 (1998).[6]

Because Oken conceded that his expert's testimony was inadmissible, all his claims failed as a matter of settled Florida state law. Thus, summary judgment was proper, federal preemption aside.

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6. "The Court need not reach the issue of causation because [Oken] failed to show any evidence that [he] can use to prove the [product] is defective." *Savage*, 31 F. Supp. 2d at 984 (citations omitted).

IV. Oken Admitted He Had "No Evidence Of Toxicity."

Oken's interrogatory answers offered in opposition to DAS's motion for summary judgment contained a fatal admission against interest. Oken quoted his treating physician's diagnosis as follows:

> Wayne was discharged with the following conclusions . . . . ***"Insecticide exposure with no evidence of toxicity. Adequate cholinesterase levels."***

While objecting to and moving to strike the remainder of Oken's offer of his interrogatory answers, DAS cross-moved for admission of this highlighted text as an admission of a party-opponent under FED. R. EVID. 801(d)(2)(A). Oken did not object to DAS's sponsorship of his admission against interest, nor did he attempt to withdraw it. Oken's solemn admission against interest, therefore, is firmly planted in the evidentiary record.[7]

Oken's factual admission that he had "[a]dequate cholinesterase levels" and "no evidence of toxicity" conclusively disproved any notion that he experienced any chlorpyrifos-related injury. The Dursban HF label prominently states:

> **NOTE TO PHYSICIAN**: Chlorpyrifos is a cholinesterase inhibitor. Treat symptomatically.

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7. In the balance of Oken's response to this interrogatory, he tried to explain away his treating physician's dispositive conclusion by making arguments that he was not competent or qualified to make. *See* FED. R. EVID. 701(c); FED. R. CIV. P. 56(e).

> If exposed, plasma and red blood cell cholinesterase tests may indicate significance of exposure (baseline data are useful).

As EPA recently explained:

> Chlorpyrifos affects the nervous system by reversibly inhibiting the activity of cholinesterase (ChE), an enzyme necessary for the proper functioning of the nervous system. Inhibition of ChE is the most sensitive effect in . . . humans, regardless of exposure duration.

EPA Toxicology Chapter for Chlorpyrifos, April 18, 2000, p. 2 (*available at* http://www.epa.gov/pesticides/op/chlorpyrifos/rev_tox.pdf).

Oken's admission that he had "no evidence of toxicity" and "[a]dequate cholinesterase levels" conclusively proved the opposite of his allegations. *E.g.*, *Pelletier v. Zweifel*, 921 F.2d 1465, 1507 (11th Cir. 1991) ("[W]hen the plaintiff's evidence conclusively proves the opposite of his allegations, summary judgment in the defendant's favor is appropriate."). Summary judgment, therefore, was appropriate, federal preemption notwithstanding.

V. Overlooking Oken's Fatal Admission Against Interest, His Concession That His Expert's Affidavit Was Inadmissible, And His Withdrawal Of His Lay Evidence, Oken's (Withdrawn) Self-Diagnosis Was Insufficient To Raise A Genuine Issue Of Material Fact As To Medical Causation.

Overlooking Oken's fatal admission against interest, his concession that his sole expert's affidavit was inadmissible, and his withdrawal of his lay and documentary evidence, Oken's (withdrawn) self-diagnosis was insufficient to raise a genuine issue of material fact. The competency requirements of FED. R. CIV. P. 56(e), and the evidentiary requirements of FED. R. EVID. 701(c) (as amended in 2000), forbade consideration of Oken's self-diagnosis on summary judgment. The law here is well-settled. *See, e.g., Kemp v. Metabolife Int'l, Inc.*, No. 00-3513, 2004 WL 2095618, at *6 (E.D. La. Sept. 13, 2004) ("Courtney is not a doctor, and therefore, as with the other Plaintiffs, she is not qualified to provide medical evidence of causation.").

> To the extent that [Plaintiffs' affidavit testimony] is a repetition of a diagnosis given her by a qualified professional, it is hearsay. To the extent it is her own opinion, there has been no showing that she is qualified to make the diagnosis . . . .

Frank v. Plaza Const. Corp, 186 F. Supp. 2d 420, 433 (S.D.N.Y. 2002) (footnotes omitted).

> If Ham's conclusions as stated in his Affidavit are based on his own self-diagnosis, then they are incompetent because there is no showing he is an expert[.] . . . [O]n the otherhand [sic], if these

> conclusions are based on what he was told by others then these statements are incompetent hearsay. Affidavits, such as this . . . are not competent summary judgment evidence.

Ham v. Lopez, No. Civ. A. SA-01-CA-936-NN, 2002 WL 31396066, at *5 (W.D. Tex. Sept. 26, 2002) (citations omitted). *See also Word v. Croce*, 169 F. Supp. 2d 219, 226 (S.D.N.Y. 2001) ("Plaintiff's self-diagnosis of irritable bowel syndrome is insufficient to support a medical condition requiring a special diet."); *Ferris v. Penn. Federation Brotherhood of Maintenance of Way Employees*, 153 F. Supp. 2d 736, 746 (E.D. Pa. 2001) ("Ferris's beliefs as to how his injuries were caused may not be presented to the jury in the absence of expert testimony regarding causation. . . ."); *Walker v. Shansky*, 28 F.3d 666, 672 (7th Cir. 1994) ("Walker's self-serving conclusions about his mental health are insufficient to withstand the defendants' motion for summary judgment. . . . [T]here is no evidence that Walker is qualified to testify as to his medical condition."); *Jackson v. Berge*, 864 F. Supp. 873, 881 (E.D. Wis. 1994) (Plaintiff "claims to have asthma and to suffer from chest pains, but he has produced no expert opinion or other competent evidence to support this self-diagnosis."); *Kayser v. Caspari*, 16 F.3d 280, 281 (8th Cir. 1994) ("Kayser's self-diagnosis alone cannot establish that he does, in fact, suffer from kidney stones. . . .").

Thus, even if Oken had not withdrawn his lay and documentary evidence, his self-diagnosis was entirely insufficient to raise a genuine issue of material fact that he suffered any injury caused by the accused products.

Similarly, Oken's self-reported symptoms allegedly occurring shortly after he used the Ortho Dursban proves nothing under Florida law. "[T]emporal proximity alone does not prove causation." *Cerna v. South Florida Bioavailability Clinic, Inc.*, 815 So. 2d 652, 656 (Fla. Dist. Ct. App. 2002). Moreover, under Florida law, "the mere occurrence of an accident does not give rise to an inference of negligence, and is not sufficient for a finding of negligence on the part of anyone." *Cassel v. Price*, 396 So. 2d 258, 264 (Fla. Dist. Ct. App.) (citations omitted), *review denied*, 407 So. 2d 1102 (Fla. 1981). Accordingly, there is not a scrap of admissible evidence to support any of Oken's claims.

VI. Oken's Failure To Offer Evidence Of A Safer, Feasible Alternative Design For The Challenged Products Doomed His Design Defect Claims As A Matter Of State Law.

Florida law requires that to make a *prima facie* case of design defect, a plaintiff must offer proof of a safer, feasible alternative design for the accused product. *See Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So. 2d 1133, 1139 (Fla. Dist. Ct. App. 2002) ("[A] product is defective in design 'when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design' and its omission 'renders the product not reasonably safe.'") (quoting RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998)). *See id.* at § 2 cmt. f ("To establish a *prima facie* case of defect, the plaintiff must prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm.").

Oken has never argued nor offered a scrap of evidence that there is a safer, feasible alternative design for the molecular structure of chlorpyrifos, for the formulation of Dursban HF, or for the formulation of Ortho Dursban. That fatal evidentiary default is yet another reason why his putative design defect claims failed as a matter of Florida state law.[8]

VII. DAS Discharged All Of Its State Law Duties To Oken As A Matter Of Black-Letter Florida Law. The Issue Of FIFRA Preemption As To DAS, Therefore, Need Not Be Reached.

In *Shell Oil Co. v. Harrison*, 425 So. 2d 67 (Fla. Dist. Ct. App. 1982), *review denied*, 436 So. 2d 98 (Fla. 1983), Shell was (like DAS is here) a manufacturer and bulk supplier of an active ingredient used by other formulators in the production and sale of over-the-counter pesticides; in that case, soil fumigants. Shell's product and its label (like Dursban HF and its label) were regulated by the EPA under FIFRA. 425 So. 2d at 68.

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8. This is another point of substantial similarity with *Bates*. There, Texas state law, like Florida state law, requires competent proof of a safer, feasible alternative design to make a *prima facie* case of design defect, negligent design, or breach of implied warranty. *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997). *See also id.* at 433 n.9; *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 n.4 (Tex. 1998); *Smith v. Louisville Ladder Corp.*, 237 F.3d 515, 521 (5th Cir.) ("[B]ecause Smith failed to establish a safer alternative design for the ladder in use at the time of the accident, his claim predicated on breach of implied warranty must fail, along with his design defect claim."), *reh'g en banc denied*, 250 F.3d 745 (5th Cir. 2001). Petitioners in *Bates*, like *Oken* here, offered no such evidence.

A container of an over-the-counter product containing Shell's active ingredient, purchased from a lawn and garden shop, fell from the shelf where it was stored, shattered, and plaintiff was injured in his efforts to clean up the spill. *Id.* at 69. Plaintiff sued "alleging negligence, strict liability and breach of an implied warranty by Shell. . . ." *Id.* at 68. The court of appeal reversed plaintiff's jury award rejecting, first, the notion that a "manufacturer and bulk supplier of a dangerous toxic component [has] a nondelegable duty to warn ultimate users of the hazards of commodities containing the toxic component when the commodities were formulated, packaged, labeled, and distributed by others[.]" *Id.* at 70. In a holding directly on point, the court then said:

> The federal regulatory system provides for EPA approval and oversight of the labeling and packaging of chemical formulations prepared for sale to the public. These labeling and packaging requirements necessarily differ depending upon the particular formulation and, thus, place the responsibility on the formulator for providing adequate warning to the public and for obtaining EPA approval. ***Shell, as the manufacturer or supplier selling in bulk to one other than an ultimate consumer, took the necessary precautions commensurate with the dangers reasonably anticipated under the circumstances.***

Id. (emphasis added).

DAS's EPA-approved Dursban HF label, exactly like the EPA-approved label described in *Shell*, "place[s] responsibility on the formulator for providing adequate warning to the public and for obtaining EPA approval."

See p. 8. Thus, "[DAS], as the manufacturer or supplier selling in bulk to one other than an ultimate consumer, took the necessary precautions commensurate with the dangers reasonably anticipated under the circumstances." 425 So. 2d at 70. Accordingly, DAS discharged all of its state law duties to Oken as a matter of black-letter Florida law and the issue of FIFRA preemption, as to DAS, need not be reached.

CONCLUSION

The petition should be denied because it presents only abstract, hypothetical and theoretical questions regarding federal preemption. Oken's entirely voluntary withdrawal of his lay and documentary evidence, his concession that his sole expert's affidavit was inadmissible, and his admission against interest that he had "no evidence of toxicity" left him with no case for federal law to preempt.

Respectfully submitted,

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